K052798

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

Submitter's Name: ISOVAC Products LLC
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Romeoville, IL 60446
Telephone: (630) 679-1740
Fax: (630) 679-1750
Contact person: Mr. Joseph Petrovic, President

JUN - 6 2006

Date of Summary: April 24, 2006

Device Names:

Trade Name: CAPSULS™ Patient Isolation Unit
Common Name: Patient Isolation Unit
Classification Name; Patient care reverse isolation chamber (21 CFR 880.5450, Product Code LGM)

Legally Marketed Device to which Equivalence is Claimed: The legally marketed predicate device is the Aircraft Transport Isolator (K790657) manufactured by Vickers America Medical Corporation, determined to be substantially equivalent to a legally marketed (preAmendment) device on July 3, 1979.

Device Description: The CAPSULS (Containment And Protection System Utilizing Life Support) Patient Isolation Unit Model 2004 is a clear, tubular, flexible, patient isolation unit (PIU) for use during transport and evacuation. Each unit employs a clear envelope (either polyurethane [PUR] or polyvinylchloride [PVC]) to allow visual monitoring of the patient; the unit also has multiple glove arms and tubular access ports to facilitate medical intervention.

The PIUs have a reinforced base mat with integrated handholds and tethers to enable lifting and attachment to a standard litter, and are supported by external ribs and end stanchions. Chamber airflow to the patient is provided by a battery-powered air-purifying respirator, which HEPA-filters contaminated air. The unit is operated under negative pressure mode during transport of a contaminated patient, and is operated in positive pressure mode during transport of a patient through a contaminated environment.

The device is used by trained medical personnel, who may or may not be licensed physicians or surgeons, and who may or may not be operating the device under the supervision of such licensed medical professionals. For this reason, ISOVAC Products intends that the CAPSULS be cleared for both prescription and over-the-counter use

Intended Use: The CAPSULS (Containment and Protection System Utilizing Life Support) is a portable Patient Isolation Unit (PIU), which prevents particulate (biological and radiological) cross-contamination between the patient and the external environment; and with features that enable medical intervention to the patient via end-user supplied medical equipment. The CAPSULS is intended to be used for:

- The transport and isolation of patients on aircraft, ambulances, ships, and any vehicle capable of safely transporting a patient on a standard litter.
- The temporary isolation, with or without transport, of patients within hospitals or other medical facilities.

Descriptive Summary of Technological Characteristics and Those of Predicate Device: The indications for use and principles of operation of the CAPSULS Patient Isolation Unit are essentially identical to those of the predicate device; however, the CAPSULS device is more versatile, lightweight, and easier to use. Differences between the devices result primarily from technological advances, such as those in materials technology and battery chemistry, which have occurred during the 26 years since the Vickers device was introduced.

Performance Data: Pressure /leak testing is conducted on all CAPSULS units prior to shipment. Applicable system level testing was conducted on the CAPSULS Patient Isolation Unit by the US government at the West Desert Test Center (WDTC) of the US Army Dugway (Utah) Proving Ground. This testing verified the isolation efficacy of the CAPSULS Patient Isolation Unit under both positive and negative pressure operational modes. Additional testing to measure differential pressure in both operating modes has been successfully conducted. CAPSULS incorporates the blower and P-100 HEPA filter cartridges of a Safety Tech International, Inc. powered air purifying respirator (PAPR) system which has been National Institute for Occupational Safety and Health (NIOSH) certified under 42 CFR Part 84, Approval of Respiratory Devices.

Conclusion: The information and data provided in this 510(k) Notification establish that the CAPSULS Patient Isolation Unit is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

ISOVAC Products, LLC
C/O Ms. Lisa S. Jones
Regulatory Affairs Consultant
Devices for the Future
540 College Street
Bellaire, Texas 77401

Re: K052798
Trade/Device Name: CAPSULS™ Patient Isolation Unit
Regulation Number: 880.5450
Regulation Name: Patient Care Reverse Isolation Chamber
Regulatory Class: II
Product Code: LGN
Dated: May 12, 2006
Received: May 15, 2006

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

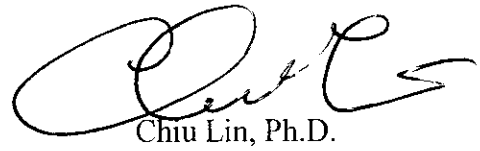
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ISOVAC Products LLC

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Indications for Use

510(k) Number: K052798

Device Name: CAPSULS™ Patient Isolation Unit

Indications for Use:

The CAPSULS™ (Containment and Protection System Utilizing Life Support) is a portable Patient Isolation Unit (PIU), which prevents particulate (biological and radiological) cross-contamination between the patient and the external environment; and with features that enable medical intervention to the patient via end-user supplied medical equipment. The CAPSULS is intended to be used for:

- The transport and isolation of patients on aircraft, ambulances, ships, and any vehicle capable of safely transporting a patient on a standard litter,
- The temporary isolation, with or without transport, of patients within hospitals or other medical facilities.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila M Murphy D 6/6/06

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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